

510(k) Summary

1C083740

Philips MammoDiagnost VU

FEB 13 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

I General Information

Company Name: Philips Medical Systems North America Company

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USA

Contact Person Lynn T. Harmer

Telephone Number: 425-478-7312

Prepared (date): 2008 November 14

Manufacturing Site: Philips Medical Systems Nederland B.V.
Veenpluis 4-6
5684 PC Best,
The Netherlands

Device Name: Philips MammoDiagnost VU

Classification Name: Picture Archiving and Communication System

Regulation number: 892.2050

Classification: Class: II

ProCode: 90 LLZ

Common/Usual Name: PACS Workstation

Predicate Devices: Stentor Inc. (now Philips Healthcare Inc.),
iSite PACS v 4.x

General Electric Medical Systems
Seno-Advantage

Hologic Inc.

SecurView DX

II Information Supporting Substantial Equivalence Determination

System Description:

Philips MammoDiagnost VU workstation software package is intended for viewing, manipulation, reporting and communication of digital mammography images (DICOM "For Presentation" images) as well as other modality images. It interfaces to mammography acquisition stations and image storage, printing and CAD devices using DICOM or similar interface standards. It uses and builds further on the Stentor iSite PACS v4.x software (Stentor is now a Philips owned company).

Philips MammoDiagnost VU workstation software package runs on standard information technology hardware and software. The proprietary software in the Philips MammoDiagnost VU workstation software package uses a standard Microsoft Operating System and user interface. Communication and data exchange are done using standard TCP/IP, DICOM and HL7 protocols.

Intended Use:

Philips MammoDiagnost VU workstation software package is intended for viewing, manipulation, reporting and communication of digital mammography images (DICOM "For Presentation" images) as well as other modality images. It interfaces to mammography acquisition stations and image storage, printing and CAD devices using DICOM or similar interface standards.

Philips MammoDiagnost VU is used with high-resolution monitors suitable for screening and diagnostic mammography, for use in the USA these monitors must be FDA cleared. It is used by trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians and assistants.

General Safety and Effectiveness:

The MammoDiagnost VU software is specified, validated and tested under a registered ISO 13485 and 21 CFR Part 820 compliant Quality System.

The MammoDiagnost VU complies with the NEMA XR 22-2006, ("Quality Control Manual" Template for Manufactures of Displays and Workstations Labeled for Final Interpretation in Full-field Digital Mammography) and to the NEMA PS 3.2 DICOM set

The device labelling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device. It is the user's responsibility to ensure that display quality, environmental lighting and other possible distractions are consistent with the clinical environment.

The hardware components specified are all "off the shelf" computer components.

Conclusion:

The Philips MammoDiagnost VU does not introduce new indications for use, nor does the use of the device result in any new potential hazard. Philips Medical Systems considers the Philips MammoDiagnost VU to be substantially equivalent to the Stentor (Philips) iSite PACS v 4.x (K063267), the GE, Seno Advantage (K033400) and the Hologic, SecurView DX (K062107)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Philips Medical Systems Nederland BV
% Ms. Melissa J. DeGuia
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Underwriters Laboratories, Inc.
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CAMAS WA 98607

FEB 13 2009

Re: K083740

Trade/Device Name: Philips MammoDiagnost VU
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 2, 2009
Received: February 3, 2009

Dear Ms. DeGuia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

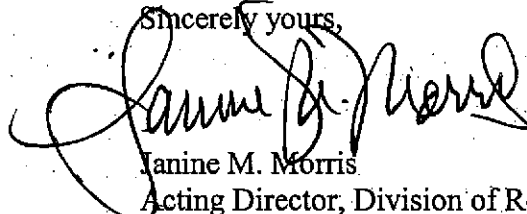
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry.support/index.html>.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(K) Number (if known): K083740

Device Name: Philips MammoDiagnost VU

Indications for Use:

Philips MammoDiagnost VU is a software workstation for viewing, manipulation, reporting and communication of digital mammography images (DICOM "For Presentation" images) and other modality images. It interfaces to image storage, printing and CAD devices using DICOM or similar interface standards.

The functional components included:

- DICOM support
- Generic hanging protocols
- Mammography hanging protocols
- CAD overlays
- Double blind read workflow
- Automatic breast tissue alignment
- Background suppression at inversion

Philips MammoDiagnost VU software runs on standard information technology hardware and software. The proprietary software in the MammoDiagnost VU product uses a standard Microsoft Operating System and user interface. Communication and data exchange are done using standard TCP/IP, DICOM and HL7 protocols.

In the USA, mammographic images may only be interpreted using FDA cleared monitors that offer at least 5 Mpixel resolution and meet other technical specifications reviewed and accepted by FDA.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

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